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**PRESS BRIEFING: WEDNESDAY, 12 JULY 2000, 08:00 local time**

# IMPORTANT ADVANCES IN STEMMING MOTHER-TO-CHILD TRANSMISSION OF HIV

**– In United States, Sharp Drop in Perinatally-Acquired HIV and AIDS; Lack of Universal Screening and Prenatal Care Pose Final Hurdles –**

**– Thai Program Demonstrates Success of Large-Scale Perinatal Prevention Program in Developing World –**

**– New Data Show Promise and Obstacles of African Perinatal Prevention; Transmission through Breast-feeding Remains High –**

*DURBAN, South Africa* – Comprehensive prevention and treatment efforts in the United States have brought sharp drops in mother-to-child (perinatal) transmission of HIV, according to new data released today by the Centers for Disease Control and Prevention (CDC), while other CDC studies demonstrate the continuing challenges in significantly reducing perinatal transmission in the developing world. The studies were discussed at a press conference hosted by CDC at the XIII International AIDS Conference.

Other CDC research in the United States examined the relationship between maternal resistance and perinatal transmission, and suggested that a combination of anti-HIV therapies might further reduce the risk of perinatal HIV transmission.

Studies from CDC-sponsored international programs highlighted new successes in international efforts to prevent perinatal transmission of HIV, as well as key obstacles to such efforts. One study documented the success of the first large-scale perinatal prevention program in Thailand in increasing access to testing and treatment. Other research, from CDC programs in Africa, found perinatal prevention efforts to be effective, but suggested that transmission through breast-feeding – and high drop-out rates in perinatal prevention programs – remained powerful obstacles to significant reduction of perinatal transmission of HIV, even when anti-HIV drugs are available.

"These studies show us how far we have come toward eliminating mother-to-child HIV transmission in the United States, and how far we have yet to go in the developing world where such efforts are urgently needed," said Helene D. Gayle, M.D., M.P.H., Director of CDC's National Center for HIV, STD, and TB Prevention and moderator of the CDC press conference.

**Perinatal Transmission Background Information**

***Transmission risk:*** In the absence of preventive drug treatment, there is a 25 to 30 percent chance that a woman will infect her newborn with HIV, either during pregnancy, during delivery, or through breast-feeding. Approximately two-thirds of perinatal infections are contracted during pregnancy or birth, and one-third are contracted through breast-feeding. It is estimated that approximately 600,000 infants are infected with HIV worldwide each year—90 percent of whom live in the developing world.

***U.S. drug regimen:*** In 1994, researchers found that a three-part AZT drug regimen could decrease the rate of perinatal transmission by approximately two-thirds. This three-part regimen – now the standard preventive treatment in the United States – consists of a course of oral AZT for three to four months prior to giving birth, intravenous AZT during delivery, and a six-week course of oral AZT given to infants following birth.

***"Short-course" regimen:*** In 1998, CDC researchers found that a shorter course of AZT is also effective, reducing the rate of transmission by approximately 50 percent. In short-course regimens, AZT is given only to the mother, and is administered orally beginning three to four weeks before delivery, throughout labor, and for one week following delivery. The short-course regimen, which is much less expensive and easier to administer than the longer course of treatment, was hailed as a major advance for women in developing countries, where access to drugs and prenatal care is extremely limited. Subsequent to these findings, another simple regimen, using a single dose of nevirapine for both mother and infant, also has proven effective in reducing perinatal transmission. Public health officials and program planners worldwide are now working to translate these findings into practice.

## KEY U.S. FINDINGS

### Declining Rates of Perinatal Transmission in the United States

Perinatal transmission of HIV dropped by half between 1993 and 1997 in 32 states that track perinatal HIV exposure and HIV infection[1], according to new data presented today by CDC epidemiologist Mary Lou Lindegren, M.D., and colleagues. The study also provides updated national data on cases of perinatally acquired AIDS, which declined 75 percent between 1992 and 1998. Declines in HIV and AIDS among children are due to successful perinatal prevention efforts and improved treatment for infected infants.

Using data from seven states[2] with enhanced HIV surveillance, Lindegren was able to identify factors contributing to continued transmission. "These data show significant progress, but they also highlight the importance of reaching all women, especially substance abusing women, with early prenatal care, HIV testing, and access to preventive therapy," said Lindegren.

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[1] Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Idaho, Indiana, Iowa, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, Wisconsin, and Wyoming. This study did not include Florida because it did not have any exposed children, or Kansas because it had just begun HIV reporting.

[2] Colorado, Indiana, Louisiana, Michigan, Missouri, New Jersey, and South Carolina

She also noted that more than one-third (35 percent) of women giving birth to HIV-infected infants were using illicit drugs. These women also will require access to substance abuse treatment. For women who seek care late in pregnancy, other interventions, such as rapid HIV testing during labor, followed by initiation of therapy, will be important. Increased education and outreach to physicians to encourage them to test all pregnant patients may also contribute to further reductions.

- **Perinatal HIV transmission falls by 50 percent in 32 states, perinatally-acquired AIDS cases by 75 percent nationally:** HIV transmission from mother to child fell by 50 percent in the 32 states reporting pediatric HIV infections from 1993 to 1997, with the incidence of perinatal HIV transmission declining from 20.7 percent in 1993 to 10.6 percent in 1997 (1998 analysis still pending). In these states, the study was able to track factors contributing to this success, including a sharp rise in the number of HIV-infected pregnant women who were tested for HIV (from 80 percent in 1994 to 96 percent in 1998), a doubling in the use of AZT among pregnant women (from 30 percent in 1994 to 69 percent in 1998), and a tripling of AZT use among exposed infants (from 27 percent in 1994 to 84 percent in 1998). The percent of women and infants receiving all three components increased from 14 percent in 1994 to 58 percent in 1998.

  Enhanced data collected from seven of the 32 states reporting pediatric HIV infection provided greater detail about those mothers who gave birth to HIV-infected infants: 17 percent received no prenatal care; 14 percent received prenatal care, but were not tested for HIV; 17 percent did not receive prenatal AZT, despite prenatal care and testing. Thirty-nine percent of the infected infants received the complete AZT regimen. ***[Abstract MoOrC239, "Progress Towards Elimination of Perinatal HIV Infection in the United States," Teresa Hammett, Oral Presentation, Monday, 10 July 2000, 16:45 (10:45 AM EDT)]***

**New Data on Viral Load, Combination Therapy and Resistance**

Additional CDC data presented here shed new light on the effect of maternal viral load and viral resistance on perinatal HIV transmission.

One study, led by CDC researcher Marc Bulterys, M.D., demonstrated that a higher level of HIV in the blood of the mother, known as maternal viral load, was the single most significant factor in those mothers who transmitted HIV to their infants. "Given this link, combination therapy, which can suppress viral load more effectively than single agents, may be our best tool for reducing the rate of mother-to-child transmission even further," said Bulterys.

The role of viral resistance in perinatal transmission was the subject of another study presented by Bulterys. The research indicates that maternal drug resistance was not associated with increased risk of perinatal transmission of HIV. Because other studies have found an increased risk of transmission among women with viral resistance, further research will be needed.

- **Risk Factors for Perinatal Transmission:** In a multi-center study of perinatal transmission in Atlanta, Baltimore, Newark, and New York City, Bulterys and colleagues examined factors influencing HIV transmission, analyzing data on infants born infected despite exposure to AZT. Over the more than four-year period examined (January 1994 to September 1998), 583 infants received AZT during pregnancy and delivery and as newborns, and 7.4 percent of these infants were infected. In addition to maternal viral load, which was the single most important predictor of transmission, the study found other risk factors associated with transmission, including more advanced disease, premature birth, and treatment with AZT alone, rather than combination antiretroviral treatment. ***[Abstract WePpC1390, "Risk Factors for Perinatal HIV-1 Transmission in Patients Receiving a 3-Part Regimen of Zidovudine Prophylaxis: The Perinatal AIDS Collaborative***

***Transmission Study (PACTS) in 4 U.S. Cities," Marc Bulterys, M.D., Oral Poster Presentation, Wednesday, 12 July 2000, 12:00 (6:00 AM EDT)]***

- **Impact of HIV Drug Resistance on Perinatal Transmission:** HIV-infected pregnant women with resistance to AZT may still reduce the risk of HIV transmission to their infants by taking the drug while pregnant. In the same four-city study (above), Bulterys and colleagues examined the impact of maternal resistance on perinatal transmission. The study examined blood samples from 167 pregnant women who received AZT during pregnancy from 1991 to 1997. While 19 percent of the blood samples showed genotypic mutation associated with AZT resistance, these resistance patterns had no demonstrable impact on transmission of the virus from mothers to infants. Tests revealed that only two children born to these mothers had viral mutations associated with drug resistance, but that these mutations were different than those of their mothers. While consistent with data from the 1994 efficacy trial of the three-part AZT regimen, these findings appear to contrast two other U.S. studies which found a higher rate of perinatal transmission among women with resistant virus. Bulterys said that because of the contrasting findings to date and the small sample size in this study, further research will be needed to confirm the effect of HIV-drug resistance on perinatal transmission. ***[Abstract TuPpB1230, "Antiretroviral (ARV) Resistance Mutations among Pregnant, HIV-infected Women and their Newborns in the U.S.: Vertical Transmission and Clades," P. Palumbo, Oral Poster Presentation, Tuesday, 11 July 2000, 12:00 (6:00 AM EDT)]***

## KEY INTERNATIONAL FINDINGS

### Perinatal Prevention Success in Thailand

Data released today demonstrated the marked success of one of the first large-scale perinatal prevention programs to be implemented in a developing country. The pilot initiative in Northeastern Thailand, conducted by the Thai Ministry of Public Health in collaboration with CDC and UNICEF, provided HIV testing to 80 percent of the 95,000

women who gave birth in this region during the period evaluated. Moreover, AZT use among infected pregnant women increased to 80 percent. Dr. Siripon Kanshana, who led the project, reported that the program's success has already led to implementation of a nationwide Thai perinatal prevention program.

"This program and others demonstrate that effective perinatal HIV prevention programs can be implemented in developing nations," said R.J. Simonds, of the HIV/AIDS Collaboration, a joint activity of the Thai Ministry of Public Health and CDC, based in Bangkok.

- **Increased Access to Prenatal Care Through Large-Scale Pilot Program:** In the pilot project led by Kanshana, the proportion of pregnant women tested for HIV increased significantly over the course of the program, from approximately 60 percent at the beginning to 80 percent by the end of the 15-month study. Even more importantly, the proportion of HIV-infected women receiving short-course AZT therapy increased from approximately 50 percent at the beginning of the program to 80 percent after only 15 months. These findings include data from July 1998 to September 1999. Data updated through March 2000, as well as efficacy results, will be presented at the conference. ***["Pilot Program to Implement Short-course AZT to Reduce Perinatal HIV Transmission in Northeastern Thailand, 1998-1999," Siripon Kanshana, Oral Presentation, Wednesday, 12 July 2000, 16:00 (10:00 AM EDT)]***

In another Thai study with international implications, CDC researchers reported that the first randomized trial in a developing country found no adverse side effects among infants exposed to the short-course AZT regimen.

- **Short-course AZT Therapy Found Safe for Children at 18 Months Follow-Up:** In a study of 196 children exposed to short-course AZT in utero and 199 unexposed children, no adverse side effects have been found to be related to the drug-regimen, according to data presented today by the Thai Ministry of Public Health, Mahidol

University, and CDC. Adverse effects among both groups were compared over the first 18 months of life. Researchers led by Tawee Chotpitayasunondh found no statistically significant differences between the groups. This study provides additional reassurance about the short-term safety of AZT in children exposed in utero. Findings are consistent with data from the U.S. and other industrialized nations which to date have found no serious short-term side effects associated with AZT exposure during labor, delivery, and infancy. Continued follow-up is important both in the U.S. and internationally to monitor for possible late effects of perinatal antiretroviral exposures. ***[Abstract ThPeC5306, "Safety of Short-course Antenatal Zidovudine for Children Born to HIV-Infected Women, Bangkok, Thailand," Tawee Chotpitayasunondh, Poster Presentation, Thursday, 13 July 2000, 11:15 (5:15 AM EDT)]***

**Perinatal Prevention Barriers in Africa**

In Côte d'Ivoire, significant cultural and economic barriers remain to effectively prevent perinatal transmission of HIV, several CDC studies revealed, even though rapid HIV testing, HIV counseling, short-course AZT, and infant formula are offered free of charge. Follow-up with HIV-infected pregnant women to provide therapy has been difficult, and many new mothers may find it difficult to abstain from breast-feeding because of a lack of family and community support. Further, formula may not be a safe option in areas where water-storage practices result in significant levels of bacteria in water. Project RETRO-CI, a co-operative program between the CDC, the Côte d'Ivoire Ministry of Health and the Institute of Tropical Medicine, carried out these studies.

- **Same-Day HIV Testing Slightly Boosts Perinatal Use of AZT:** Although rapid HIV testing with same-day counseling and test results increased the proportion of pregnant African women who received their HIV test results, it only slightly increased the proportion of infected women taking short-course AZT therapy, according to a CDC study of 15,125 women in a prenatal clinic in Abidjan. The researchers, led by Toussaint Severin Sibailly, had believed that removing the two-

week wait for standard (ELISA) HIV test results might significantly increase the number of women receiving preventive treatment, since only 46 percent of those testing positive with the ELISA test were returning for their results. Use of the rapid test did significantly increase the number of women learning their results – 90 percent of the infected women stayed to receive their test results. Preliminary findings show that the proportion of women receiving AZT remains low due to a high number of women who were lost to follow-up prior to 36 weeks gestation, when therapy can begin. Overall, a slightly higher percentage of infected women (19 percent) tested with the rapid HIV test, compared with 12.6 percent with the standard test, ultimately received the short-course AZT treatment, indicating that lack of knowledge of HIV status is not the only barrier to delivering short-course therapy. ***[Abstract WeOrC549, "Impact of On-site HIV Rapid Testing with Same-day Post-Test Counseling on Acceptance of Short-course Zidovudine for the Prevention of Mother-to-Child Transmission of HIV in Abidjan, Côte d'Ivoire," Oral Presentation, Wednesday, 12 July 2000, 15:00 (9:00 AM EDT)]***

**Breast-Feeding a Major Impediment to Reducing HIV Transmission**

Additional CDC studies – the majority in Côte d'Ivoire – showed that short-course AZT can significantly reduce the risk of perinatal HIV transmission overall, even in breast-feeding populations, but that the therapy does not appear to reduce the risk of postnatal transmission. Because transmission through breast-feeding does offset some of the reduction in transmission achieved by AZT therapy before and during birth, safe and acceptable alternatives to breast-feeding remain critical.

Breast-feeding is a customary practice in West Africa with an average duration of nearly 14 months. In many places in sub-Saharan Africa, it also is a necessity for women who are unable to afford infant formula or do not have access to clean water to prepare formula.

"Breast-feeding transmits HIV, but remains a difficult practice to replace, particularly with the lack of viable alternatives," said CDC researcher Stefan Wiktor, M.D., who discussed the Project RETRO-CI findings.

- **Postnatal Transmission Through Breast-feeding:** In analyzing data from two clinical trials conducted in the West African cities of Abidjan, Côte d'Ivoire and Bobo-Dioulasso, Burkina-Faso, CDC researchers found that short-course AZT significantly reduced the overall risk of perinatal HIV transmission, despite having no impact on postnatal transmission. Many of the infants born uninfected became infected by the age of two through breast-feeding. At six weeks of age, 14 percent of infants whose mothers took AZT were infected with HIV, compared to 23 percent of the children whose mothers did not take AZT – a 40 percent reduction with short-course AZT. At two years, 22 percent of children whose mothers took AZT were infected, while 30 percent of children whose mothers did not take AZT were infected – a 27 percent reduction with short-course AZT. The studies, authored by Wiktor and colleagues, found that there was no statistical difference in the risk of postnatal HIV transmission from mother to infant between the two groups, with just over nine percent (9.4 percent) of the 354 women given short-course AZT transmitting infection through breast-feeding, compared to nearly nine percent (8.6 percent) of the 357 women in the control group. While the results show that short-course AZT given to the women alone does reduce perinatal transmission, the high risk of postnatal HIV transmission highlights the need to develop additional interventions to prevent this mode of transmission. Data from Burkina-Faso was provided by the Agence Nationale de Recherche sur le SIDA. ***[Abstract TuOrB354, "24-month Efficacy of Short-course Maternal Zidovudine for the Prevention of Mother-to-Child HIV-1 Transmission in a Breast-feeding Population: A Pooled Analysis of Two Randomized Clinical Trials in West Africa," Stefan Wiktor, M.D., Oral Presentation, Tuesday, 11 July 2000, 15:15 (9:15 AM EDT)]***

- **Barriers to Replacement Feeding:** A survey of 120 households in Abidjan conducted by CDC researcher Hortense Angoran, M.D., and colleagues, found that water storage practices are important to examine when considering replacement feeding to prevent perinatal transmission. All the households studied had access to safe municipal drinking water at a community tap and 93 percent (112) of households used this water, either directly or by storing it in a container. Stored water was much more susceptible to contamination. Of the houses that stored water, researchers detected *E. coli* in 41 percent of household water samples. At the time of the interview, the youngest child was regularly drinking stored water in 74 percent (89) of households. Only three percent (3) of mothers treated drinking water for the youngest child; all three did so by boiling the water. The study highlights the need for sanitary water cans to reduce the risk of diarrheal disease in infants, particularly in places where many women are encouraged to use replacement feeding (formula) to reduce transmission of HIV. ***[Abstract WePpC1316, "Implications of Household Water Storage Practices on Replacement Feeding of Children Born to HIV-Infected Women, Abidjan, Côte d'Ivoire," Hortense Angoran, M.D., Oral Poster Presentation, Wednesday, 12 July 2000, 11:30 (5:30 AM EDT)]***

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